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EXAMINER	
FUBARA, BLESSING M	
ART UNIT	PAPER NUMBER
1618	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/938,667	PETERSEN, JENS	
	Examiner	Art Unit	
	Blessing M. Fubara	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 May 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9-17,29-32,34-38,52,53,62,67-69,78-80 and 82-90* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9-17,29-32,34-38,52,53,62,67-69,78-80 and 82-90* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/24/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Examiner acknowledges receipt of amendment, remarks, request for extension of time and IDS filed 5/24/2007. Applicant added new claims 85-90; canceled claims 54, 55, 57, 63 and 81. Claims 9-17, 29-32, 34-38, 52, 53, 62, 67-69, 78-80 and 82-90 are thus pending in the application.

1. Previous rejections that are not reiterated herein are withdrawn.

The Claims as amended on 5/24/07:

Claim 9 is drawn to method of treating urinary incontinence, the method "comprises increasing resistance of passage through a urethra comprising administering prosthetic device that comprises "hydrogel, comprising about 0.5 to 25% by weight based on the total weight of the hydrogel, of a polymer prepared by a method comprising combining acrylamide and methylene bis-acrylamide: wherein the hydrogel includes less than 50 ppm monomeric units, has a complex viscosities of about 2-50 Pas and has an elastic modulus of about 1-200 Pa."

"Prepared by a method ... bis-acrylamide," is the process of preparing the acrylamide hydrogel. "Less than 50 ppm monomeric units" in the hydrogel represent residual amounts of the starting acrylamide monomer and the cross-linker methylene bis-acrylamide. The viscosity and the elastic modulus are inherent properties of the hydrogel.

Claim 78 is similar to claim 9 except that specific mode of administration of the acrylamide hydrogel is recited in claim 78, which is injected into the urethra.

Claim 79 is similar to claims 9 and 78.

Claim 80 is similar to claim 9 except that the urethra is bulked by administering prosthetic device.

New claim 85 is similar to claim 9 except that administration of prosthetic device provides adequate resistance in a urethra. "Adequate resistance" is relative and given to artisan's judgment of what is adequate.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 9-17, 29-32, 34-38, 52, 53, 62, 67-69, 78-80 and 82-90 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pavlyk (US 5,798,096) in view of RU 2148957 and applicants admission (interview of 2/23/06 and remarks filed 2/27/06) and further in view of Annis et al. (US 4,857,041).

Generic claims 9 and 78-80 are analyzed above as described under "**The Claims**:" It is noted in the analysis for claim 9 that the method of treating urinary incontinence comprises administering to the urethra. Claim 79 injects the hydrogel into urethra. Claims 78 and 80 administer the endoprosthesis and increasing the resistance of the urethra and bulking are intended uses of the hydrogel. The other aspects of the properties of the hydrogel as described for claim 9 is the same for the claims 78-80.

Pavlyk discloses cross-linked polyacrylamide hydrogel (claims 52 and 53) produced from acrylamide and methylene bis-acrylamide monomers and apyrogenic or pyrogen free water

(abstract; Table 1) meeting the limitations of the acrylamide hydrogels and pyrogen free water of the claims; the hydrogel is used as endoprosthesis by way of sterile injections into tissues by way of canals of the corporum cavernosum (column 1, lines 5-10; column 10, lines 37-56). Pavlyk discloses that the hydrogel provides bulking (column 3, lines 17-18); the hydrogel of Pavlyk has low viscosity (column 2, lines 58-67) and the Pavlyk hydrogel would inherently have the viscosity properties recited. The amount of the acrylamide in the hydrogel ranges from 3.5 to 9.0% touching pints along the claimed acrylamide range of 0.5 to 25% as in the generic claims 9 and 78-80. The hydrogel of Pavlyk would inherently exhibit the intended use of the claimed hydrogel and would have the claimed properties since a product and its properties cannot be separated and thus meets claims 13, 35, 36, 67-69. The 3.5% acrylamide of Pavlyk is less than 15%, 10%, 7.5%, 5% (claims 11, 29-31) and 3.5% is at least 1%, 1.6% (claims 12, 34). The amount of water or aqueous solution in Pavlyk ranges from 88% to 96% (see Table 1) meeting the water limitation of claims 14, 62 and Pavlyk's use of pyrogen free water meets claims 63. Since the reaction between the acrylamide monomer and the methylene bis-acrylamide monomer cross-linking agent goes to completion, since the Pavlyk reference does not disclose the presence of residual monomeric units in the acrylamide hydrogel, and since the residual monomer in the product is expected to be very minimal if any, Pavlyk renders less than 50 ppm monomeric unit obvious.

While Pavlyk discloses injecting the hydrogel into caverns that may meet canals or conduits or channels, and if the cavern does not specifically read on channels or tubes, it is known according to the RU reference 2,148,957 and as admitted by applicant that the acrylamide of Pavlyk is known and used for injection into the ostium of the ureter in the treatment of urinary

incontinence (see paragraph of remarks filed 10/27/06), with injecting meeting claims 78 and 79. Furthermore, it is known in the art that urinary incontinence is treated by administering prosthetic device comprising polyacrylamide hydrogel into the urethra (Annis at abstract; column 2, lines 65-68; column 3, lines 12-23). Therefore, it would have been obvious to one of ordinary skill in the art to inject hydrogel into the caverns that would inherently act as a bulking agent or increasing the resistance of passage of urine through the caverns. One having ordinary skill in the art would have been motivated to inject the acrylamide hydrogel into the ostium of the ureter or the urethra with the expectation that the hydrogel would act as a bulking material that would create increased resistance to the flow urine in the urethra or the ureter that would lead to the treatment of urinary incontinence.

Response to Arguments

4. Applicant's arguments filed 5/24/07 have been fully considered but they are not persuasive.

Applicant argues that a) the prosthetic device performs no physiological/biological function because Pavlyk does not teach using the polyacrylamide gel to treat urinary incontinence, b) the RU reference does not also treat urinary incontinence because the RU reference uses the hydrogel to impede the normal passive flow of urine from the kidney through the ureter and then to the bladder.

Response:

Regarding a), examiner agrees with applicant that Pavlyk does not say that acrylamide is used to treat urinary incontinence and that is why the rejection is made in combination with other references, such as applicant's admitted prior art and Annis, that render the claimed process

obvious. Regarding b), it is noted that if the acrylamide of the RU reference, which as per applicant is the same scope as that administered by Pavlyk, impedes the flow of urine, then the acrylamide of Pavlyk would also impede urine flow when administered to portions of the urinary tract. In this respect also, it is known in the art as disclosed by Annis, that prosthetic device comprising acrylamide is administered to the urethra to treat urinary incontinence.

5. Claims 9-17, 29-32, 34-38, 52, 53, 62, 67-69, 78-80 and 82-90 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vogel et al. (US 6,335,028) in view of RU 2148957 and applicants admission (interview of 2/23/06 and remarks filed 2/27/06) and further in view of Annis et al. (US 4,857,041).

Vogel discloses method of treating urinary incontinence by administering, by injection into esophageal wall or via the urethra and into the wall of the bladder sphincter and urethral wall, acrylamide based hydrogel produced with about 25 to about 98% methacrylamide and about 2-about 50% methylene bis-acrylamide and containing autologous cells (abstract; column 4, lines 31, 32, 51-67; column 6, lines 1-16; column 10, lines 40-44; Examples 1 and 2); sterile and pyrogen free injectable solutions are employed for the storage of the hydrogel product (column 6, lines 58-60). Since the Vogel reference does not disclose the presence of residual monomeric units in the acrylamide hydrogel, and since the residual monomer in the product is expected to be very minimal if any, Vogel renders less than 50 ppm monomeric unit obvious.

Vogel discloses injectable acrylamide based hydrogel, and being injectable, it would have inherent viscosity that is characteristic of injectable hydrogels such as the claimed viscosities. The hydrogel contains cells (column 4, line 57) or other active agents (column 10, lines 54-67). The viscosity and modulus of elasticity are properties of the hydrogel. The amount of the polyacrylamide would approximate the amount recited since the starting amount of the acrylamide is at about 25% and the expected amount of the end product would be less than the starting 25%. Vogel does not state that the hydrogel is a prosthesis. But it is known that acrylamide based hydrogels are used as endoprosthesis for administration into the ostium of the ureter for treating urinary incontinence according to RU 2148957 and applicant's admission (interview of 2/23/06 and remarks filed 2/27/06) and further that Annis discloses treating urinary incontinence is treated by administering prosthetic device comprising polyacrylamide hydrogel into the urethra (abstract; column 2, lines 65-68; column 3, lines 12-23). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to inject the cross-linked polyacrylamide based hydrogel of Vogel through the urethra to treat urinary incontinence. One having ordinary skill in the art would have been motivated to administer the hydrogel of Vogel as a prosthetic device according to the teachings of Annis, the RU reference or applicant's admitted prior art with the expectation bulking the urethra to treat urinary incontinence.

Response to Arguments

6. Applicant's arguments filed 5/24/07 have been fully considered but they are not persuasive.

Applicant argues that a) Vogel does not teach complex viscosity and that the RU reference does not provide elements of complex viscosity to the acrylamide of Vogel, b) that one would not be motivated to use the hydrogel of the RU reference in the Vogel because of the difference in passive function of the ureter and active function of urethra, c) there would not be reasonable expectation of success using the gel of the RU reference for treating urinary incontinence.

Response:

Regarding a), complex viscosity is an inherent property of the hydrogel, and in this case the acrylamide hydrogel so that the hydrogel of Vogel would inherently have complex viscosity and applicant has not factually shown that the acrylamide composition of Vogel would not have complex viscosity. Regarding b), the RU reference is relied upon for a teaching that acrylamide impedes the flow of urine in the urinary tract as admitted by applicant and as stated by applicant in the remarks filed 5/24/07. Furthermore, Annis teaches administering prosthesis comprising acrylamide into the urethra to treat urinary incontinence. Regarding c) success is expected because it is known in the art that administering acrylamide to the urethra treats urinary incontinence (Annis at abstract; column 2, lines 65-68; column 3, lines 12-23).

Suggestion:

It was suggested to applicant, as was suggested previously and as stated on page 8 of applicant's remarks of 10/20/06, that the hydrogel be injected into urethra at 0.5 cm distally from the neck of the bladder to overcome the art, explanation of why that position provides unusual

and unexpected result may be necessary. Please not that Vogel injects hydrogel of the type claimed into the urethra.

It is noted that applicant has not commented on the above suggestion.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

8. Claims 9-17, 29-32, 34-38, 52, 53, 62, 67-69, 82-84 and 86-90 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 9 recites "increasing resistance of passage through a urethra" and it is not clear what is passing through the urethra that experiences increased resistance.

It is suggested that, if the resistance is created against the passage of urine, applicant may claim such. The claims are vague for not identifying what is passing through the urethra.

No claim is allowed.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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